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Regulatory issues for validation and qualification for new human-on-a-chip systems

It is well known that the cost of drug discovery and subsequent regulatory approval for each new candidate now exceeds $2B and in most cases requires 10-15 years of development time before general availability is granted by either the FDA or EMA. The industry would benefit greatly from better pre-clinical screening technologies to reduce the attrition rate during clinical trials as well as to begin to pre-select specific genetic sub-populations for optimal drug efficacy with limited distribution. A promising technology to help reduce the cost and time of this process are body-on-a-chip or human-on-a-chip systems either at the single organ level or more advanced systems where multiple organ mimics are integrated to allow organ to organ communication and interaction. There is currently a focus at the NIH, FDA and EMA to understand how one could validate these systems such that qualification could be granted for their use to augment and possibly replace animal studies. This talk will give examples of some of the more advanced body-on-a-chip systems being developed as well as the results of five workshops held at NIH as collaboration between the American Institute for Medical and Biological Engineering (AIMBE) and NIH to explore what is needed for validation and qualification of these new systems.

Biography

James J Hickman is the Founding Director of the NanoScience Technology Center and a Professor of Nanoscience Technology, Chemistry, Biomolecular Science, Material Science and Electrical Engineering at the University of Central Florida. Previously, he held the position of the Hunter Endowed Chair in the Bioengineering Department at Clemson University. He completed his PhD from the Massachusetts Institute of Technology in Chemistry. For the past 25 years, he has been studying the interaction of biological species with modified surfaces, first in industry and in the latter years in academia. While in industry he established one of the first bioelectronics labs in the country that focused on cell-based sensors and their integration with electronic devices and MEMS devices. He is interested in creating hybrid systems for biosensor and biological computation applications and the creation of functional *in vitro* systems for human body-on-a-chip applications. He has worked at NSF and DARPA in the area of biological computation. He is also the Founder and current Chief Scientist of a biotechnology company, Hesperos, which is focusing on cell-based systems for drug discovery and toxicity. He has 111 publications and 18 book chapters, in addition to 26 patents.

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